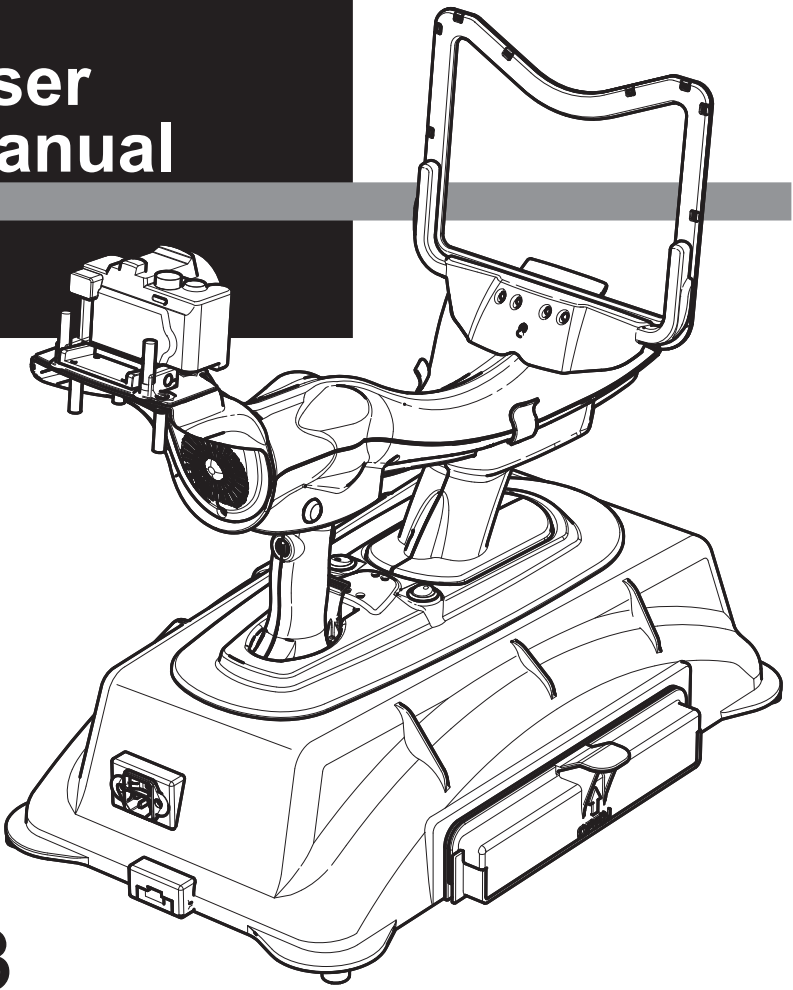
DYNAMIC
ANGIOTHERMOGRAPHYC

Aura

Breast *Life*

EN

User Manual



CE
0123

Please read the safety precautions carefully

Identification 01

1.0 - Manual identification
1.1 - Manufacturer identification
1.2 - Product identification
1.3 - CE marking

01 Identification

1.0 - Manual identification

Please read this manual carefully before use.
In particular, all employees assigned to use of the device must read the instructions for using it safely.
In the event of any difficulty, please contact the support team.

User manual code: _____ Date of issue: _____

VALIDATION	COMPANY ROLE	SIGNATURE	DATE
Checked by	Quality manager		
Reviewed by	Legal representative		

1.1 - Manufacturer identification

Please read this manual carefully before use.
In particular, all employees assigned to use of the device must read the instructions for using it safely.

In the event of any difficulty, please contact the support team.

01 Identification

1.2 - Product identification

The Aura medical device is an electromedical device.
The device conforms to the requirements of Directive 93/42/EEC, Appendix II.

Model:	Aura
Version:	55910A0
Device category:	2A
Manufactured by:	BREAST LIFE S.R.L.

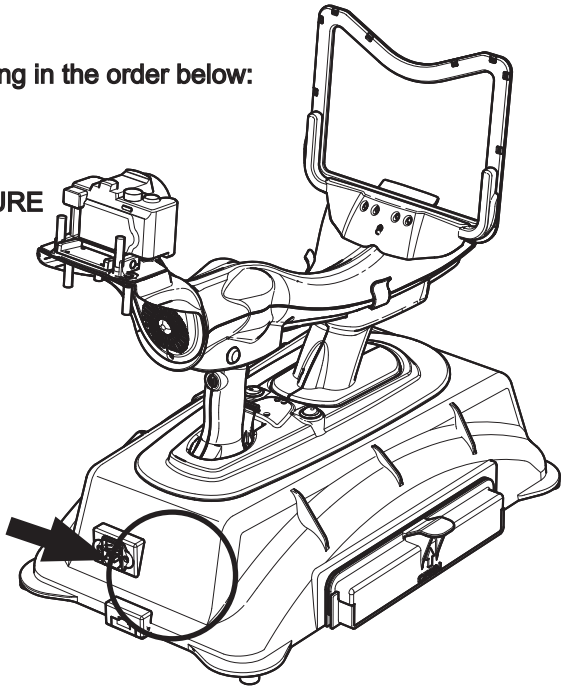
BREAST LIFE S.R.L.
PIAZZA SAN MARTINO,1
40126 BOLOGNA - ITALIA

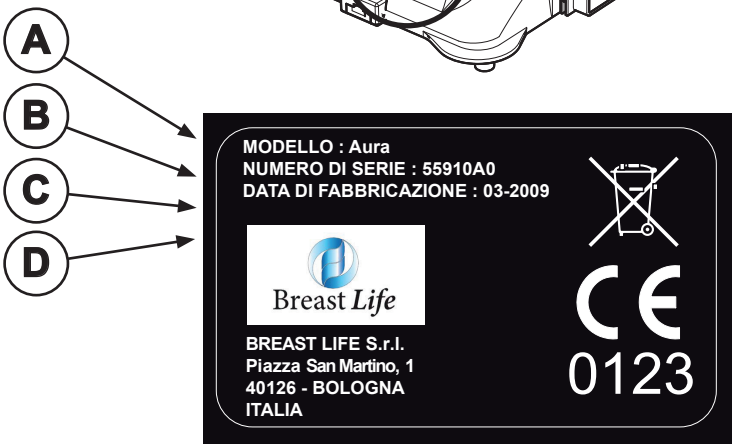
1.3 - CE marking

The plate bearing the CE marking is placed where shown in the illustration, as per the specifications in Appendix XII to Directive 93/42/EEC.

The plate shows the following in the order below:

A - MODEL
B - SERIAL NUMBER
C - DATE OF MANUFACTURE
D - INPUT (*supply voltage*)





01 Identification

Package contents

02

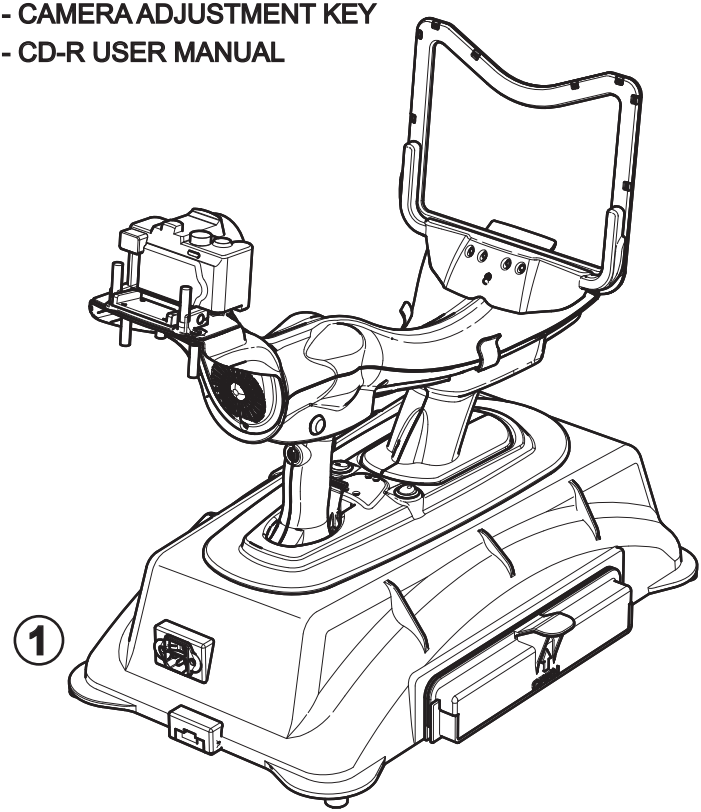
2.0 - Package contents
2.1 - Accessories provided
2.2 - Optional accessories

02 Package contents

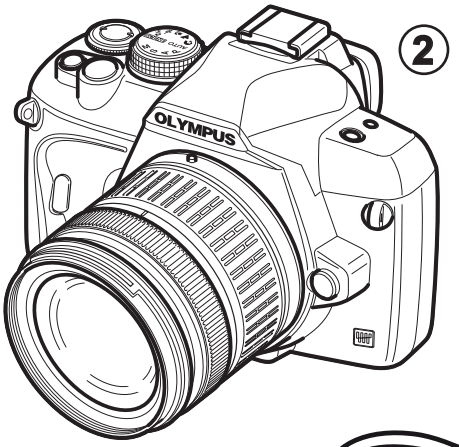
2.0 - Package contents

The device packaging contains the following items.
If any of the package contents are missing or damaged, please contact your retailer.

1 - AURA
2 - CAMERA
3 - AC CABLE
4 - PLATES
4a - PLATE 33,5° C / 92.3° F (COLD - BLACK FRAME)
4b - PLATE 32° C / 89.6° F (WARM - WHITE FRAME)
5 - CAMERA ADJUSTMENT KEY
6 - CD-R USER MANUAL



Package contents



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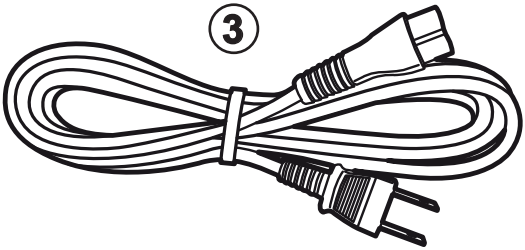
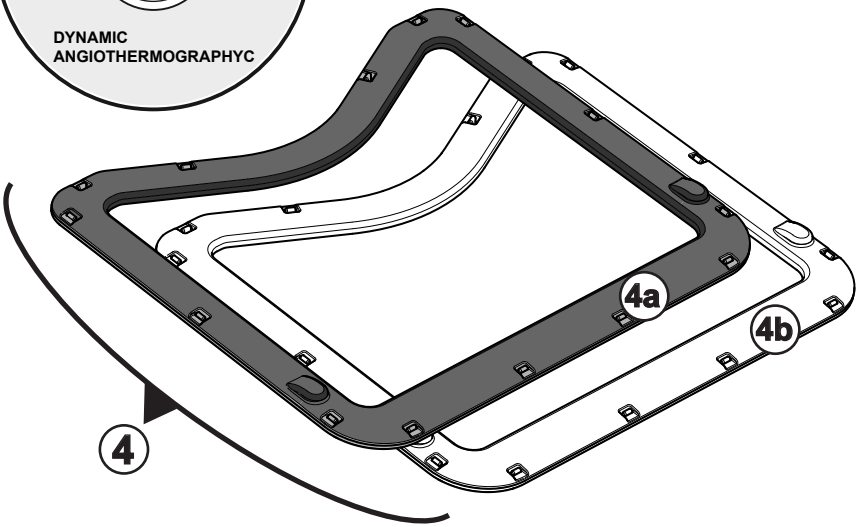


3

6

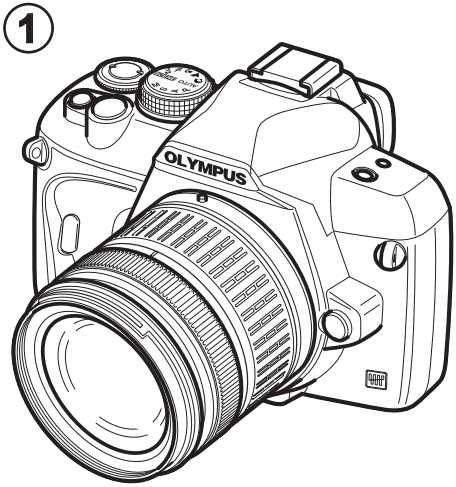


02 Package contents

2.1 - Accessories provided

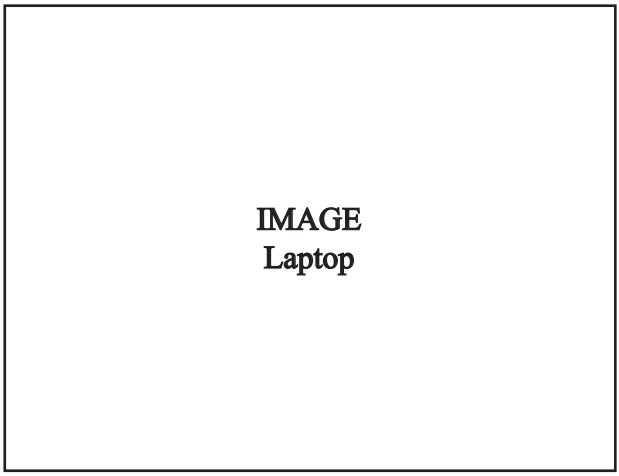
In addition to the items provided, the packaging includes the following accessories.
If any of the packaging contents are missing or damaged, the conditions referred to above apply.

1 - CAMERA



2.2 - Optional accessories

Inclusion of the following device in the package can be requested as an accessory.
If any of the packaging contents are missing or damaged, the conditions referred to above apply.



02 Package contents

Intended use 03

3.0 - Warnings and precautions for use
3.0.1 - Instructing personnel working with the machine
3.0.2 - Safety notices
3.0.1 - Obligations of personnel working with the machine
3.0.4 - Safety measures for use
3.0.5 - Safety information
3.1 - Packaging, lifting and transport
3.2 - Installation
3.2.1 - Customer responsibilities
3.2.2 - Electrical connection
3.2.3 - Temperature and humidity
3.2.4 - Preparing the device
3.3 - Contraindications

03 Intended use

Intended use

The AURA device enables mammary injuries to be diagnosed using the dynamic angiothermographic technique.

The technique is not a replacement for mammography, but is a supplement to it to increase the sensitivity of diagnosis in breast treatment.
It is a non-invasive technique which can be applied to women of any age and it is readily repeatable, painless and risk-free.

The AURA is a genuinely promising diagnostic instrument for assessing even young patients with high mammary gland density and for preventive purposes.

3.0 - Warnings and precautions for use

The AURA device must only be used in a suitably equipped hospital department or doctor's surgery.

The doctor using it is responsible for the proper, safe use of the device, with particular reference to the following points:

- the device is designed for a permanent electrical installation. The quality of the electricity supply system must be the usual level for commercial or hospital premises.

If the user requires continuous operation during power cuts, it is advisable to equip the AURA with an uninterruptible power supply (UPS) or a battery.

The device requires particular precautions regarding the EMC and must be installed in accordance with the EMC information contained in the accompanying documentation.

Do not use the device in the proximity of mobile and portable radio communication equipment in order to avoid any disturbance to the behaviour of the medical appliance.

03 Intended use

3.0.1 - Instructing personnel working with the machine

Use of the medical device must be restricted to medical personnel; these personnel, due to their experience and professional level, will be able to make the correct choices in order to achieve the desired effects.
We recommend that all operators and support personnel are provided with adequate instruction on safety standards and that a suitable instruction and/or update programme is adopted.

3.0.2 - Safety notices

Knowledge of the general safety instructions and applicable law enables the device to be used safely and correctly.
This manual provides important information on the safe use of the machine, particularly safety instructions which must be followed by all persons involved in the use of the device.

Attention must be paid to all the applicable accident-prevention rules in the country and site where the device is installed and used, and these rules must be followed.

03 Intended use

3.0.3 - Obligations of personnel working with the machine

Before starting to operate this medical devcie, all persons involved undertake to:

- pay attention to all accident-prevention rules applicable to the environment in which they are operating
- carefully read this manual in relation to safety aspects.

3.0.4 - Safety measures for use

Only medical personnel may use the device.
Inexpert or not fully trained persons may use the device only if they are accompaned by an expert and under the responsibility of the expert.

Only technical support personnel may intervene in the electronics.
If intervention is required on the electronics of the device, at least one more support person must be present.
Specific accident-prevention labels are placed on the guards on the areas where particular dangers apply.

03 Intended use

3.0.5 - Safety information

This user manual must always be easily consultable at the site where the device is in use.
In addition, all signs and information labels must always be kept in good condition.

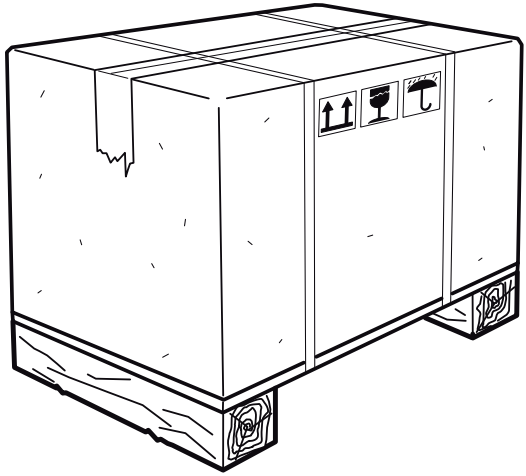
3.1 - Packaging, lifting and transport

The AURA device is provided in a special cardboard pack with a wooden base, all closed with suitable straps and adhesive tape for packing.
Protective moulds are provided inside to avoid any damage.
All lifting and transport operations must be carried out in accordance with the applicable accident-prevention instructions.
The packaged equipment must be moved using appropriate means of lifting and transportation (transpallets, forklift trucks, etc.). The personnel involved must wear all the accident-prevention protective equipment required during these operations.

IMPORTANT

Follow the instructions in the pictograms on the outside of the packaging.

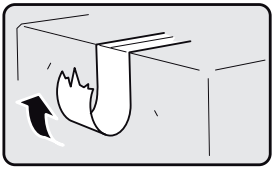
BREAST LIFE S.R.L. cannot be held liable for damage to persons or property arising due to total or partial failure to comply with the appropriate precautions to be applied in lifting and transporting the package.

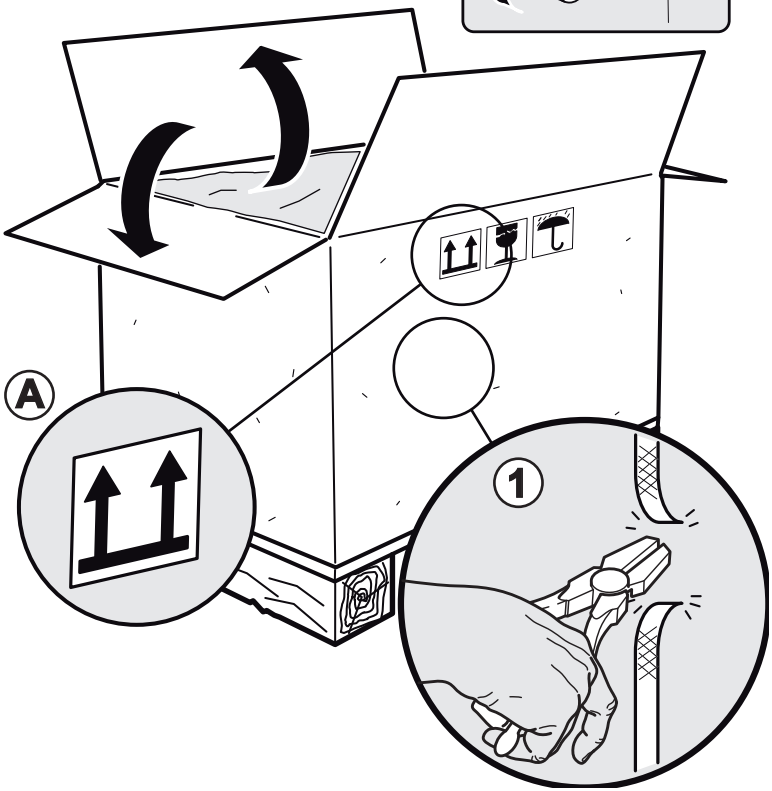


03 Intended use

Place the package in a site which facilitates unpacking of its contents, positioning it as indicated on the pictogram at (**A**).
Cut the straps (**1**) using suitable tools and remove the adhesive tape on the upper part.
Open the packing strips and take out the contents with the top covering and the lateral guards still in place.

Separate out the packing residues and the packaging itself, then comply with the rules applicable in the country of use regarding disposal of packaging waste.





3.2 - Installation

3.2.1 - Customer responsibilities

Before installation, the area and site where the device is to be located must be properly prepared.
The designated site must ensure correct installation and be large enough to enable all the phases of use.

The socket for connection to the power grid must comply with the requirements of the country where the device is being installed.

Finally, a suitable operating environment must be provided. Details on this are provided in the following paragraphs.

3.2.2 - Electrical connection

The device must be connected to the electrical system in accordance with the applicable electrical safety requirements. In accordance with the applicable European standards, the device is normally provided with a supply cable and “Schuko” type plug as per the CEI 23-50 standard.

3.2.3 - Temperature and humidity

To ensure that the device functions correctly the temperature must be between 50 and 104°F.

03 Intended use

3.2.4 - Preparing the device

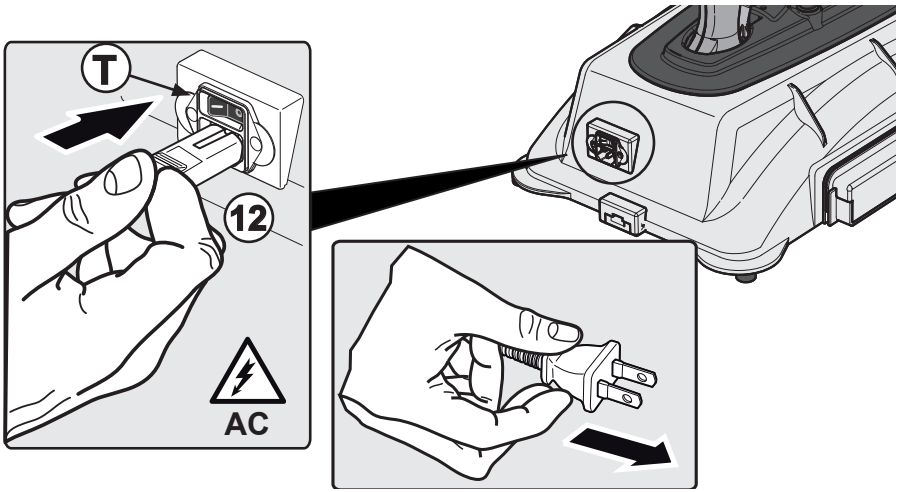
Having taken the device out of the covering and its protective equipment, place it at the intended site.
The site must have a perfectly stable, flat base and there must be an AC socket for the power supply.
In addition, the position of the device must ensure that it is easy to use.

ELECTRICAL CONNECTION

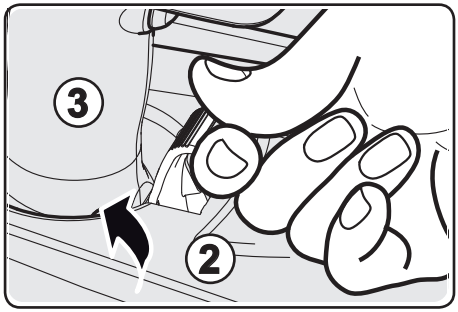
Connect the supply cable (see package) to the AC socket (**12**), and to the power grid socket.
Press switch (**T**) to turn on the device.
Check that the LED (**L1**) on the plate unit (**8**) comes on.

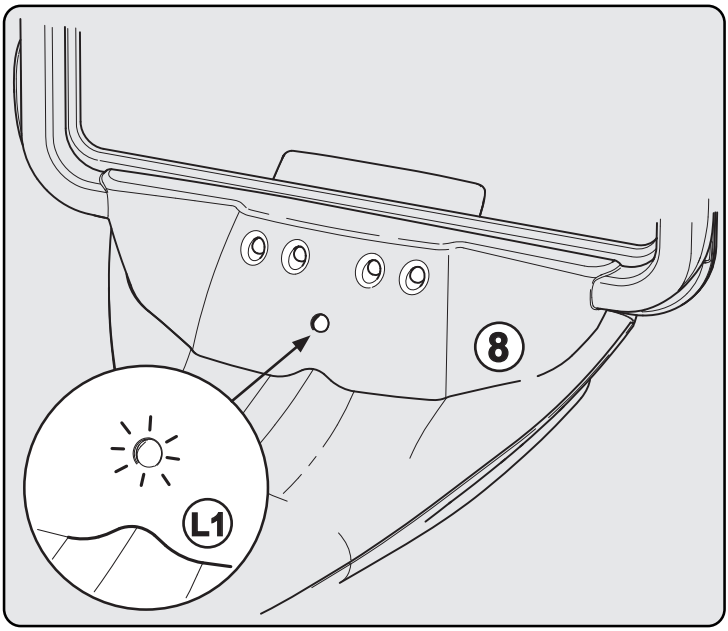
BATTERY RECHARGING

Charge indicator
RED LED: charging in progress
GREEN LED: recharging complete
ORANGE LED: running out of battery
(recharging time: approx. 3 hours and 30 minutes)



Check that the sleeve unit (3) is properly placed in the seat of the recharging base unit (2) and fixed in place with the appropriate lock as shown in the illustration.





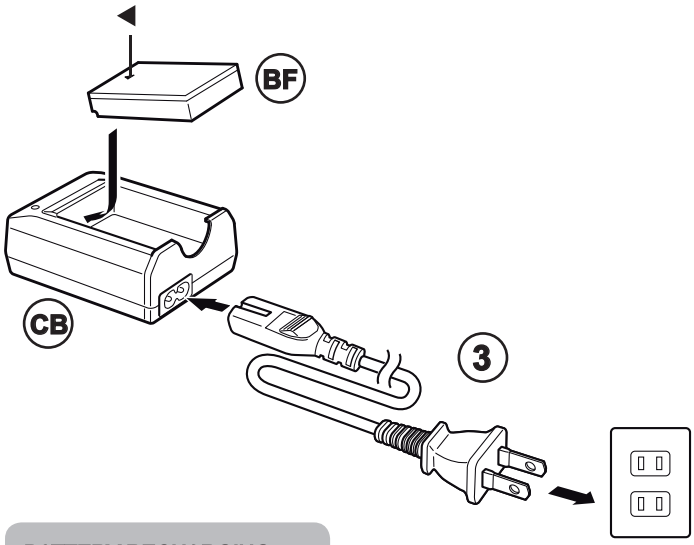
03 Intended use

CAMERA

The AURA device is provided with a camera and a support for it. Proceed as follows to prepare it for operation.

BATTERY CHARGING

Inside the camera package (*see accessories provided*), you will find the camera battery (**BF**), the battery charger (**CB**) and a supply cable for it (**3**).
Prepare the parts as shown in the illustration, then connect the plug to the power grid and wait until the battery has fully charged.

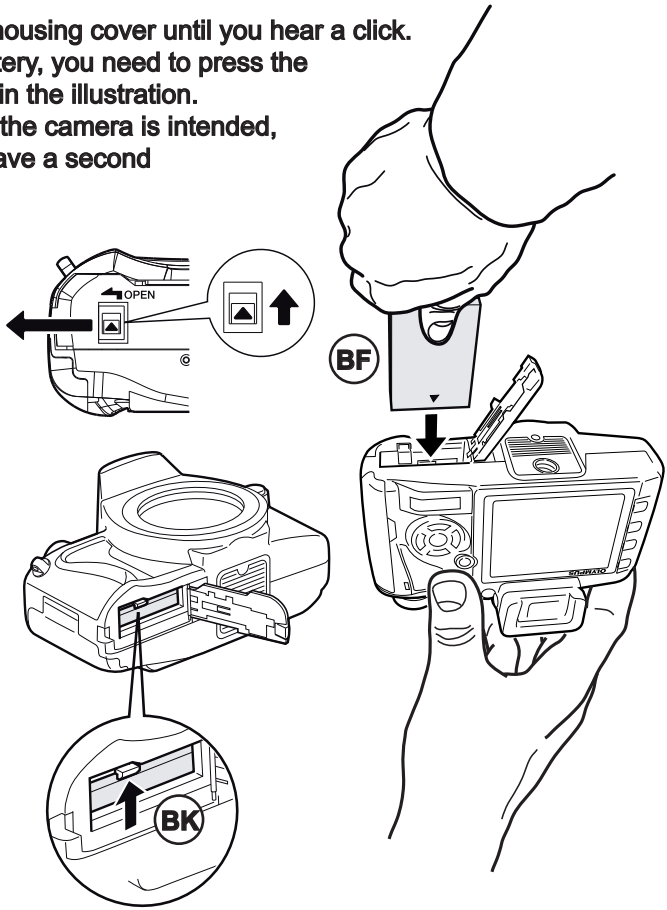


BATTERY RECHARGING

Charge indicator
RED LED: charging in progress
GREEN LED: recharging complete
ORANGE LED: running out of battery
(recharging time: approx. 3 hours and 30 minutes)

INSERTING THE BATTERY INTO THE CAMERA

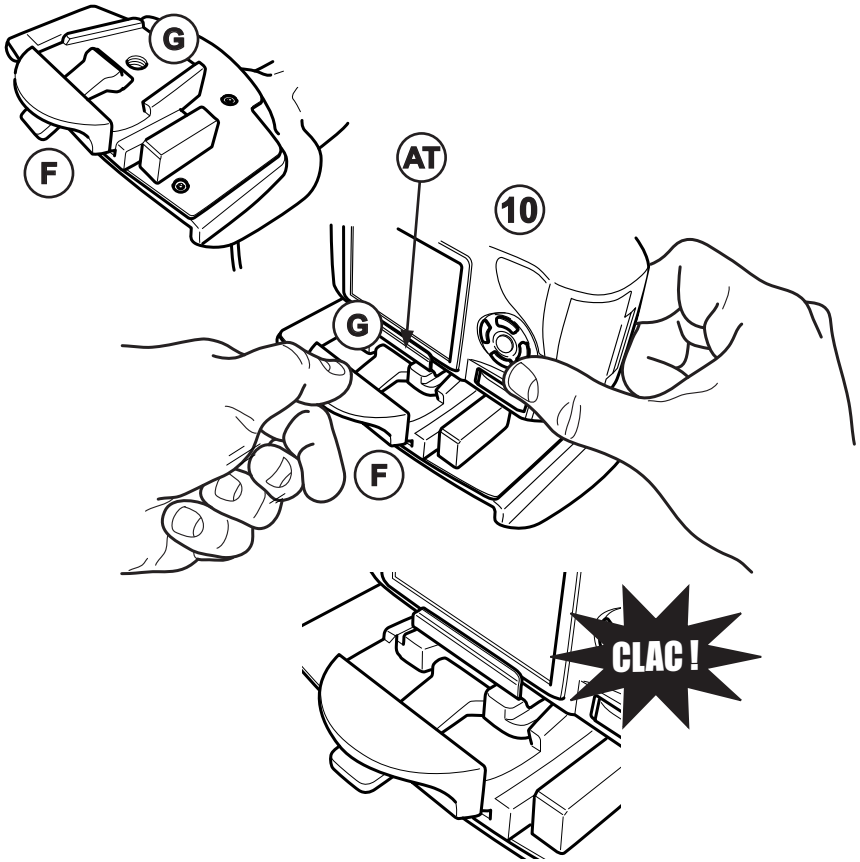
Having completed the charging process, remove the battery (**BF**) from the battery charger and disconnect the supply cable from the power grid.
Fix the camera in place then hold it firmly and rotate it 180°.
Open the cover and insert the battery (**BF**) in the housing, ensuring it is the right way up.
To ensure it is in place correctly, follow the instructions in the illustration.
Close the battery housing cover until you hear a click.
To remove the battery, you need to press the block (**BK**) shown in the illustration.
If extended use of the camera is intended, it is advisable to have a second battery in reserve.



03 Intended use

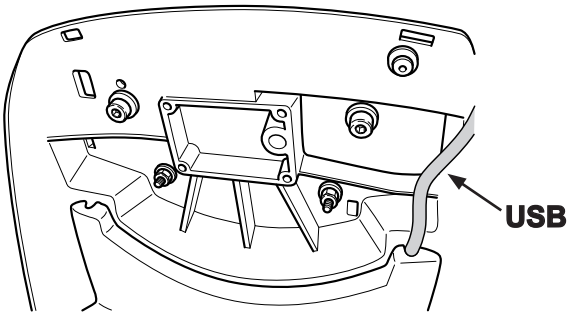
MOUNTING THE CAMERA

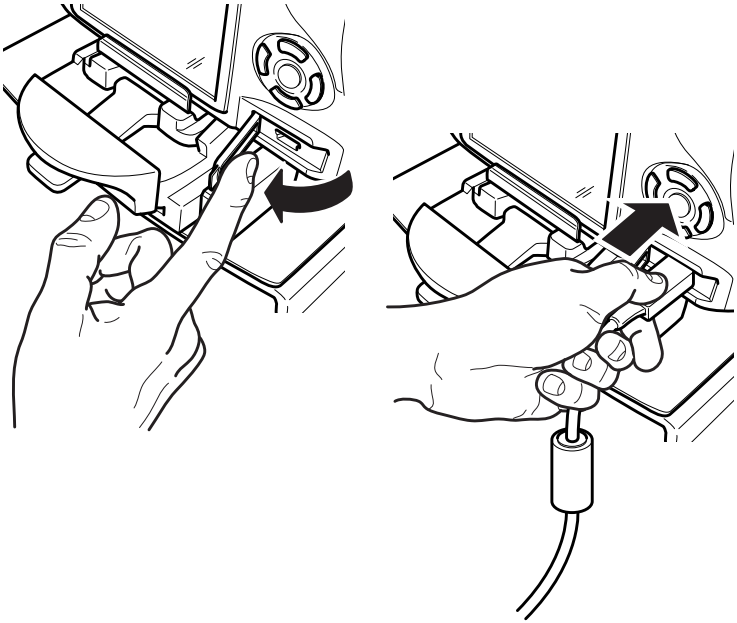
Carry out the installation as described below.
Insert the attachment (**AT**) under the camera (**10**) in the appropriate guides (**G**) in the support, by first pressing the end of the lock (**F**), then inserting the camera as shown in the illustration until you hear a loud click to indicate that mounting is complete.



CONNECTING THE CAMERA'S USB CABLE

The USB cable is located in the lower part of the support, in the position indicated in the figure.
Open the lock to access the multi-connector then insert the end of the cable into the socket.

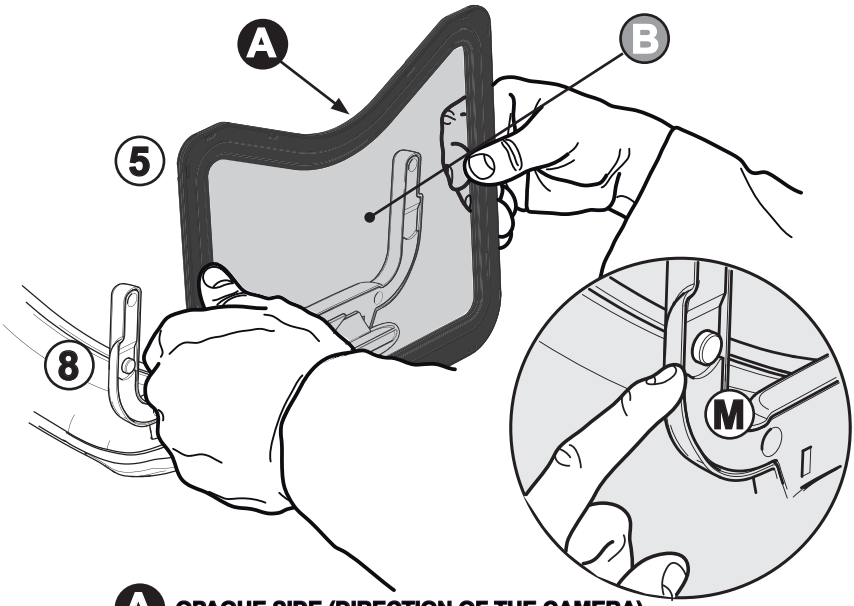




03 Intended use

PLATE ASSEMBLY

Grip the plate (5) and position it on the support (8) where the magnets (M) are located, making sure beforehand that the opaque part of the plate is facing in the direction of the camera lens.
Check that the plate is fitted correctly on the support; if it is not, repeat the operation.



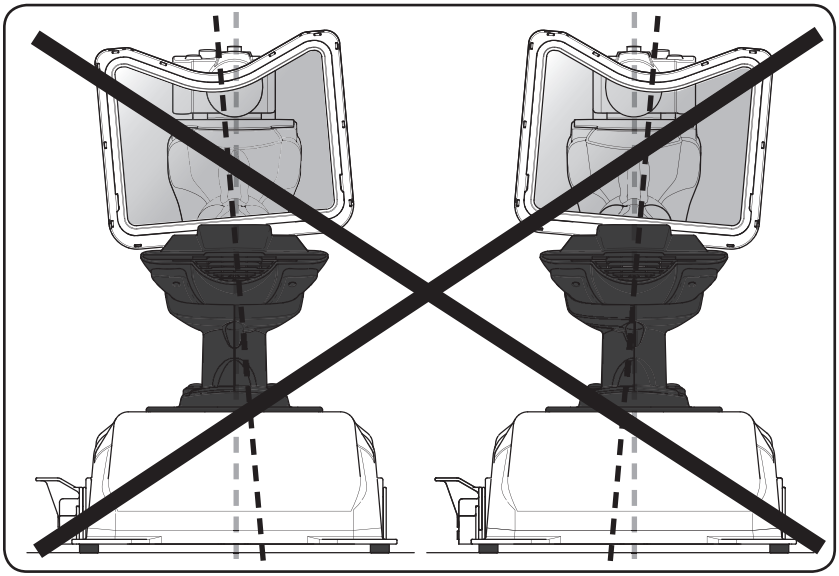
A **OPAQUE SIDE (DIRECTION OF THE CAMERA)**

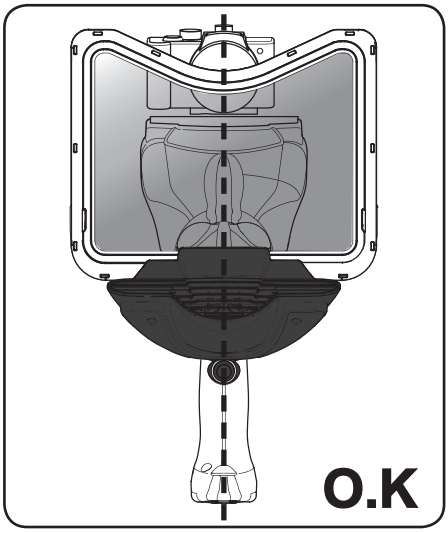
B **SHINY SIDE (DIRECTION OF THE PATIENT)**

WARNING

IN HANDLING THE PLATE PAY PARTICULAR ATTENTION NOT TO TOUCH THE OPAQUE SIDE (A) OF THE FILM WITH YOUR HANDS. GRIP IT HOLDING IT BY THE FRAME AS SHOWN IN THE FIGURE

POSITIONING DIAGRAM





03 Intended use

ANGIOTHERMOGRAPHIC PLATE

The angiothermographic plate consists of a thin and rigid support that stretches a very thin sheet of plastic material, on which a layer of black paint and a layer of cholesterine liquid crystals are applied.
The entire assembly has a thickness of a few hundredths of mm.
In this way the plate can rapidly acquire the cutaneous heat and cool down just as quickly until it returns to the basic conditions.
The formation and the disappearance of the image (which take place by supporting and distancing the plate on/from the breast), occur in fractions of a second.

Manufactured in this way, it is also capable of maintaining a spatial resolution constantly lower than 0.03/0.39 Inc. during the whole time required for reading, interpreting and recording the image.
This capability is provided by liquid crystals that partially refract the light, in proportion to the heat received, due to their particular molecular structure.

The cholesterol liquid crystals are organic crystals derived from cholesterol and their spiral molecular structure expands and contracts as the temperature changes.
These crystals can therefore be formulated and calibrated to change colour at specific temperatures.
They reflect the light that they receive, in a series of colours in sequence, namely red, green and blue.

The microencapsulation process encloses the liquid crystal in microspheres, thereby protecting it from external agents.
The microencapsulated liquid crystals always show the change in colour in the same way and order, with speeds that vary depending on the extent of the temperature scale.
The available precision is +/-32.9°F, for medical products.

Intended use

Available temperatures range from -22°F to +248°F.
The microencapsulated liquid crystals always assume the same colouring at the formation of the image, and in a reversible way, thereby allowing the use of these indicators repeatedly, with precision and consistency.

The possibility of detecting even minimal differences in temperature of any given body, by applying an ELC-coated plate to that body, is extremely useful in the diagnosis of even minimal variations of the organ examined.

The plates supplied as standard are of two temperatures:

92.3° F PLATE (COLD - BLACK FRAME)
89.6° F PLATE (WARM - WHITE FRAME)

The temperature difference is very important.
To examine young patients, the colder 92.3°F plate is used, while when visiting patients in or close to menopause, it is preferable to use the more sensitive 89.6°F plate.
(see CHAP.01 - Paragraph 2.0 - Contents of the Package)

The plate is positioned on a supporting device which also has the following functions:

• cooling, in order to eliminate the disturbance action to the diagnosis procured from superficial veins

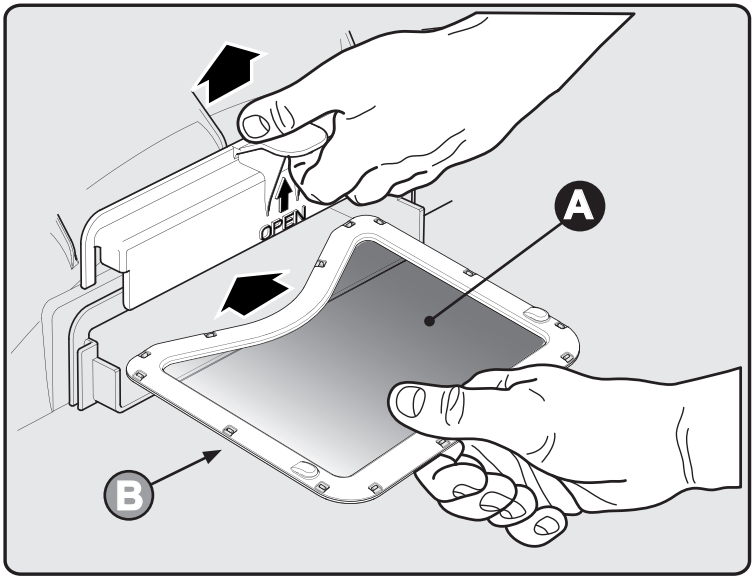
03 Intended use

It is important to observe certain precautions when handling the plate, both during and after use in diagnosis procedures.

To avoid any damage, we recommend that at the end of the process you replace the plate inside the compartment provided in the base of the device.

When handling the plates, we recommend that you hold them by the external frame and avoid touching the opaque, internal part (A).
Insert them in the corresponding tray, positioning them as illustrated in the figure.

ATTENTION!
DO NOT EXPOSE TO EXCESSIVE HEAT SOURCES



A OPAQUE SIDE (FACING UP)

B SHINY SIDE (FACING DOWN)

3.3 - Contraindications

As it is not a radiological technique, it can even be used during pregnancy.
The image which is obtained is an image with a greater scope but without the presence of new vessels, at the end of pregnancy and breast-feeding the image will return to the basic image.
This consistency of the image even during pregnancy can be useful for identifying neoplasias of the breast related to pregnancy, which is very difficult to do in any other way.

Breast radiotherapy after breast cancer makes it difficult to produce a correct diagnosis on the remaining parenchyma (*to assess any local relapses*) for at least six months, as the oedema and the inflamed state caused by radiotherapy mask the presence of new tumour vessels.

Cream
Ultrasound gel
The presence of body cream or ultrasound gel may compromise the correct diagnosis as it can create a filter between the plate and the vascularization of the mammary gland

The DATG technique can be used at any point during the menstrual cycle

03 Intended use

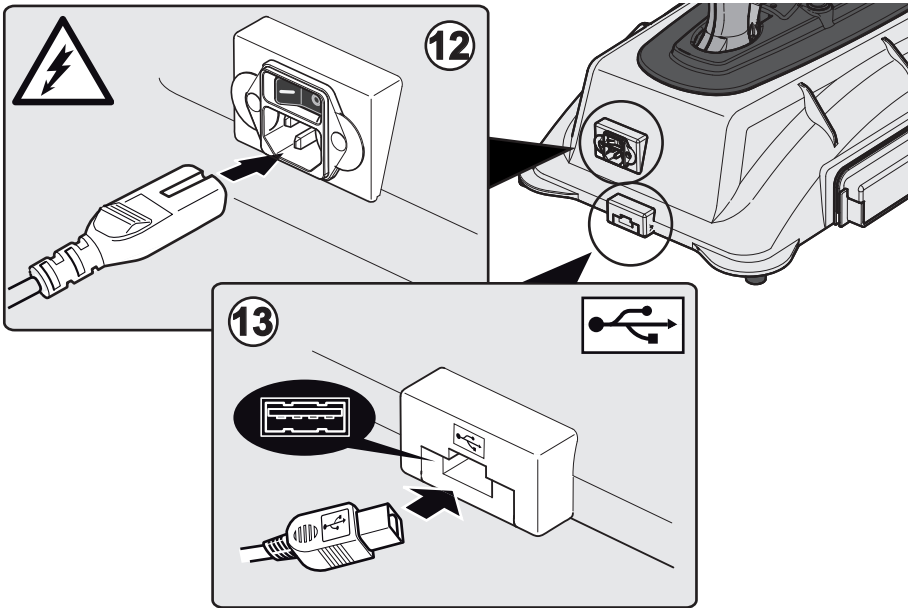
4.0 - Usage
4.0.1 - Description of the device
4.1 - Operating sequence
4.1.1 - Area identification
4.2 - Re-use procedures
4.3 - Disposal

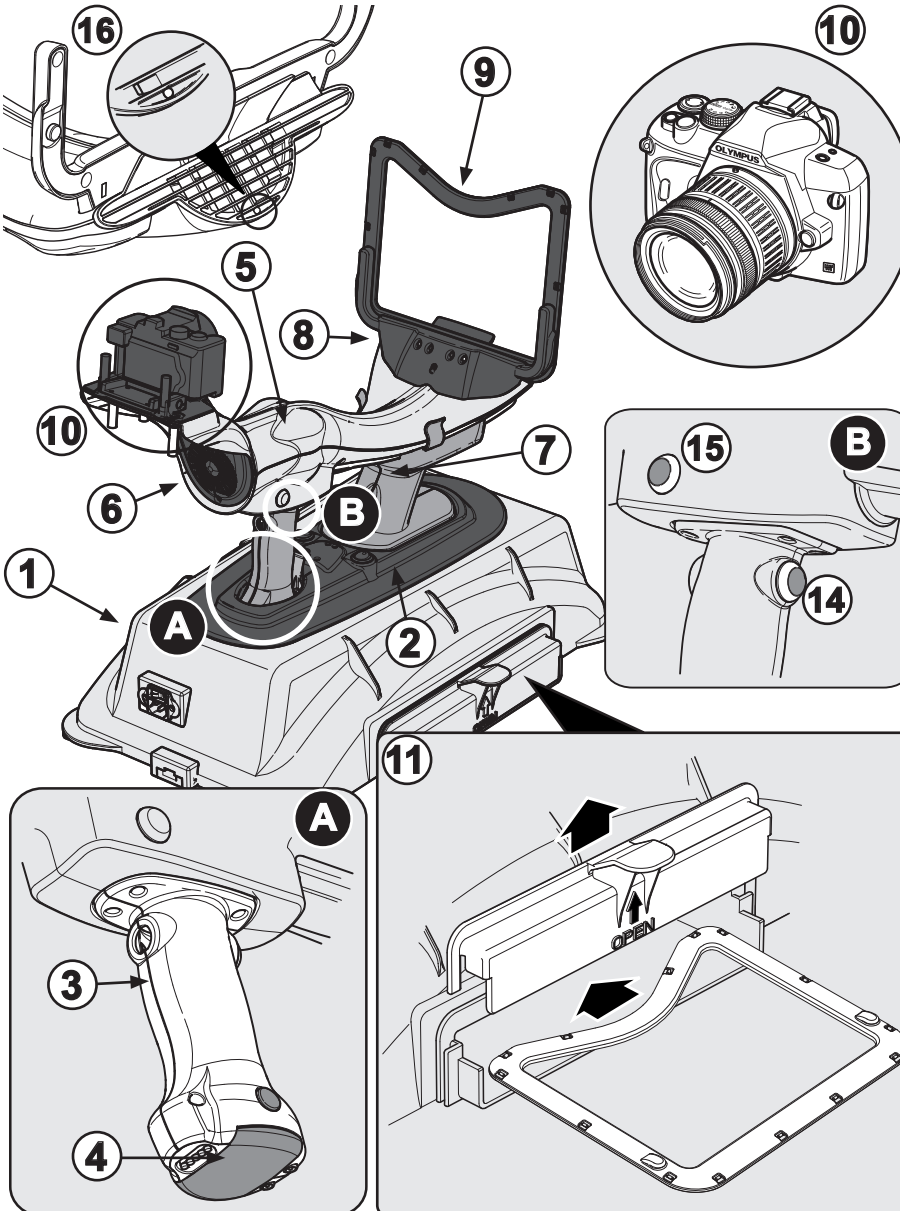
04 Usage

4.0 - Usage
4.0.1 - Description of the device

Having removed the device and accessory parts from the packing, place it on a previously prepared surface.
The AURA device consists of the following parts:

1 - BASE UNIT
2 - CHARGER BASE UNIT
3 - SLEEVE UNIT
4 - BATTERY UNIT
5 - ARM BODY UNIT
6 - FAN
7 - SUPPORT
8 - PLATE UNIT
9 - PLATE
10 - CAMERA
11 - PLATE CONTAINER
12 - AC SOCKET
13 - USB SOCKET
14 - FAN SWITCH
15 - LED SEQUENCE SWITCH
16 - AIR FLOW INDICATOR LED




16
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6
B
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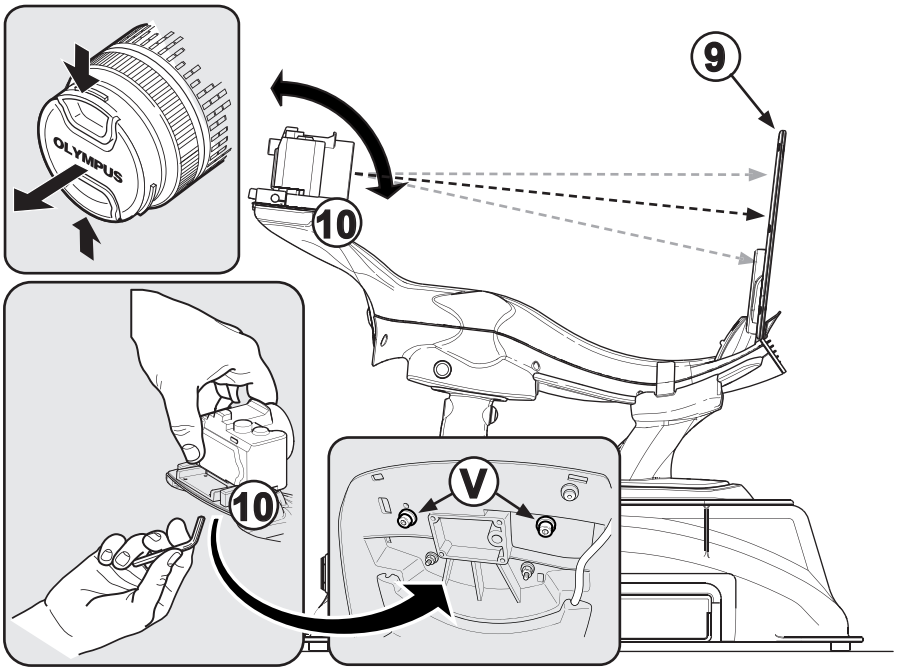
1
A
14
2
11
A
OPEN
3
4

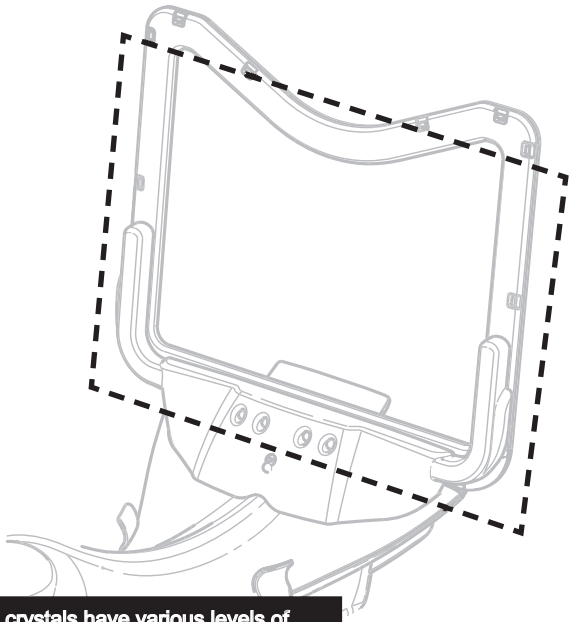
04 Usage

4.0 - Operating sequence

Having installed the device as described in chapter 03 - Installation, before using the AURA the following checks must be made.
Check that the LED (**L1**) (*see 3.2.4 - Preparing the device*) is green.
Check that the plate (**9**) is mounted correctly on the support and that it is the correct type (*visualisation power**).
Check the direction of the camera (**10**) in relation to the plate (*alignment*).
If necessary, adjust the locking screws (**V**) under the support, using a suitable wrench (see pack).
Loosen them as far as necessary to direct the camera in relation to the plate.



They must be adjusted in such a way that the area to be photographed includes both the plate area and the LEDs underneath, as shown by the dotted lines in the illustration.
When adjustment is complete, retighten the screws (V).
At this point, the lens cover can be removed and the diagnosis operations can be performed.



* VISUALISATION POWER

The industrially encapsulated liquid crystals have various levels of sensitivity as a result of which they react to the heat received (from red to violet) according to various ranges.
This ensures that the plates have different visualisation powers.
Plates calibrated in various ways must therefore be prepared.
It is up to the operator to select the one most suitable to the case in question.

ALIGNMENT

Alignment is simply a matter of adjusting the angle of the camera in relation to the plate, or more precisely adjusting the field of the camera in relation to the area to be photographed.
It is performed during assembly by the manufacturer.
After adjustment, the adjustment screws (V) under the support are tightened and locked with paint.
It may be the case that due to settling, expansion as a result of variations in temperature, etc., the alignment is no longer optimal and must therefore be reset to the factory settings.

04 Usage

Uncouple the arm by releasing the lock, then lift it off the charging base unit by grasping it with your left hand

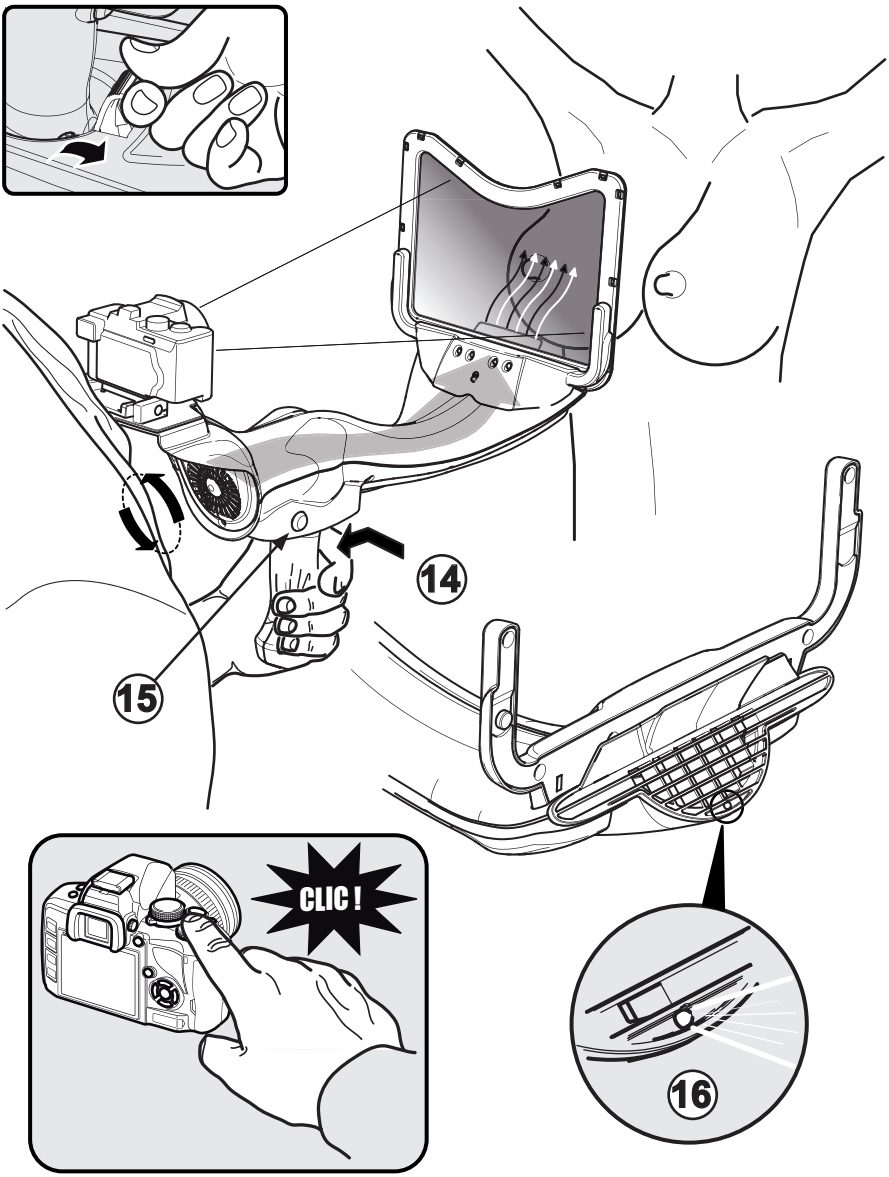
Move the arm towards the breast, then press button (14) to activate the cooling fan, and the LED (16), which illuminates the area where the cooling air flow is to be directed by a beam of light.
Cooling must last for a period between 5 and 15 seconds.

Having created the right conditions, place the plate on the breast, the press button (15) with your right hand to activate the LED (12) (see Par. 4.1.1. – Area identification) and press the camera button, again with your right hand, to take the photograph.

Proceed in the same way in accordance with the sequence described below.
Normally the procedure involves examining the lateral quadrants of the right breast, followed by the front quadrants, followed by the front quadrants of the left breast, then the lateral quadrants.

Each time a photograph is taken it must correspond to a quadrant and one of the LEDs present on the plate support must light up.
Pressing the button (15) in sequence illuminates the next LED and extinguishes the preceding one.
This enables the operator to monitor the photographic sequence (see Par.4.1.1 – Area identification)

We recommend positioning a light source behind the doctor carrying out the examination.


14
15
CLIC !
16

EXAMINATION WITH DYNAMIC ANGIOTHERMOGRAPHY

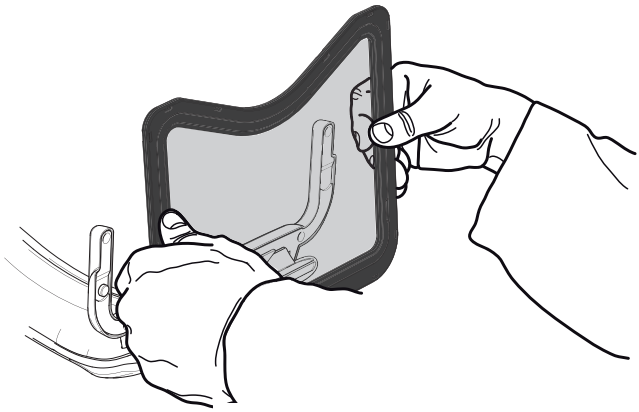
1 – Accurate anamnesis
2 – Clinical examination of breasts and lymphoid stations
3 – Position the angiothermographic plate and evaluate the sequence and strength of the angiothermographic signs
4 - Cool
5 – Position the plate again and evaluate the angiothermographic signs again
6 – Carry out a mental subtraction
7 - Evaluate:

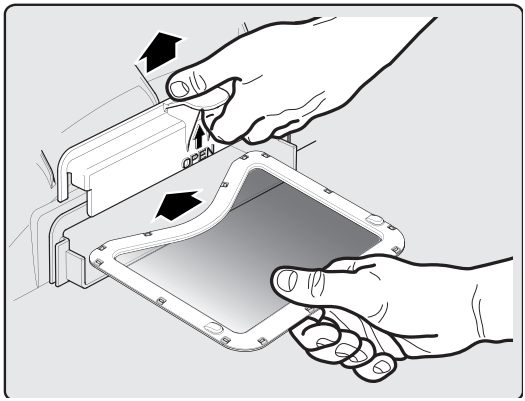
Symmetry (counter-lateral proportionality)
Regularity of the peduncles:

a) Form (pointed termination)
b) Location (in the anatomic quadrant of the peduncle)
c) Appearance of the image

The image, allowing for “subtraction” of the venous background noise
8 – Correspondence between CLINICAL-DYNAMIC ANGIOTHERMOGRAPHIC examinations
9 – Correspondence between MAMMOGRAM-ECOGRAM-DYNAMIC ANGIOTHERMOGRAPHIC examination

Once the diagnosis has been completed, reposition the arm by inserting the handle into its housing in the front of the support; recouple the arm again using the lock
Remove the plate from the support, grasping it by its frame, and replace it in the plate holder tray (see CAP.03 Par. 3.2.4 – Preparing the PLACCA ANGIOTHERMOGRAPHIC PLATE device)





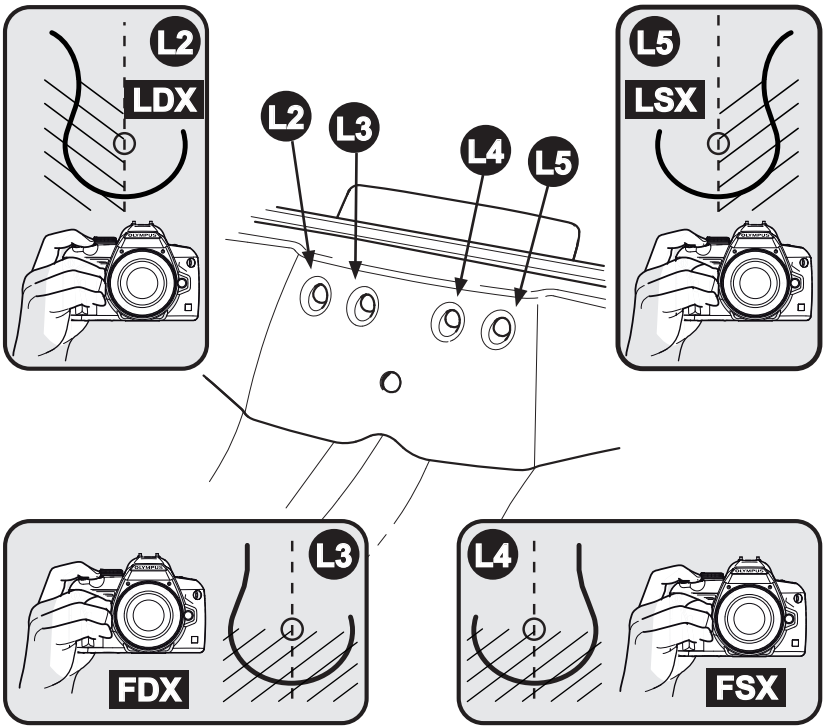
Connect the USB cable to the socket (13) (see 4.0.1 – Description of the Device) located in the base of the device, then transfer the images to the patient's file on the computer.

4.1.1 - Area identification

The series of LEDs on the plate unit enables the photographic sequence of the four areas of the breast to be established as they progressively light up.
Each LED corresponds to an area of the left breast and the right breast.

The key below shows the correspondence between the LEDs and the four areas of the breast.

L2 - LEFT SIDE OF BREAST
L3 - LEFT FRONT OF BREAST
L4 - RIGHT SIDE OF BREAST
L5 - RIGHT FRONT OF BREAST



4.2 - Re-use procedures

Once the operational procedure is complete, the procedures for maintaining the device in conditions in which it can be re-used fully efficiently must be followed.
Special attention must be paid to how the operator is to:

a) check the integrity of the device and its components (power cable, applied and electrified parts, etc.);
b) clean the device and its applied parts.

If a period of extended inactivity is planned, the AC power cable must be disconnected from the power grid and from the device itself (*see 3.2.4 - Preparing the device - ELECTRICAL CONNECTION*).
Then place it in a dry, obstacle-free place in order to avoid any damage.
Cover the device with a sheet or something similar.

4.3 - Disposal

At the end of the operating life of the device, all its parts must be disposed of in accordance with the applicable legislation in the user's country regarding the disposal of electromedical instruments and equipment.

5.0 - Maintenance

05 Maintenance

5.0 - Maintenance

To ensure efficient operation and maintenance of the device in conditions of total efficiency and safety, the information in the table below must be complied with.

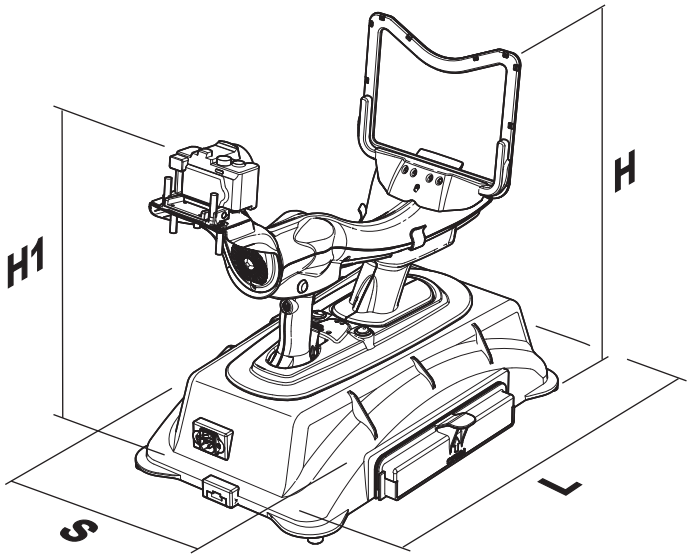
FREQUENCY	DESCRIPTION	PERSONNEL	EQUIPMENT
EVERY 2 MONTHS	FAN CLEANING	OPERATOR	ASPIRATOR
EVERY MONTH	CHECK BATTERY SUPPLIER	OPERATOR	
ON EVERY USE	EXTERNAL PARTS CLEANING	OPERATOR	MULTIPURPOSE DETERGENT
ON EVERY USE	PLATE CLEANING	OPERATOR	ALCOOL

6.0 - Technical data
6.0.1 - General specifications
6.0.2 - Device specifications

06 Technical data

6.0 - Technical data

6.0.1 - General specifications



ITEM	SPECIFICATIONS
SUPPLY	220 V / 50+60 Hz / 10 A
DIMENSIONS (mm / Inc)	630 (L) X 530 (H) (H1=580) X 350 (S) 24.8 (L) X 20.8 (H) (H1=22.8) X 13.7 (S)
INDICATIVE WEIGHT	6 Kg / 13.2 lb
OPERATING TEMP.	15+35 °C / 59+95 ° F
STORAGE TEMP.	min.5-max.45 'C / 41-113' F
DEVICE CLASS	2A CLASS